US Patent Application No. 10/608,166 Alan Mautone
COMPLETE CLAIM LISTING

I claim:

1. (Presently Amended) A process for preparing a eustachian tube lumen patency and pressure equalization performance enhancing medicament comprising:

combining one or more lipid surfactants, one or more spreading agents and one or more propellants to form a mixture, said lipids and said spreading agents being selected from the group consisting of sterols, lipids, fatty acids, cholesteryl esters, phospholipids, carbohydrates, and proteins, all in powder form, wherein said lipids and said spreading agents are insoluble in the propellants and said lipid surfactants are selected to be present in an amount effective in reducing surface tension of an air/liquid interface resident upon epithelial tissue lining the lumen of the eustachian tube and said spreading agents are selected to be present in an amount effective in distributing said surfactant within said lumen when said propellants are evaporated from said mixture to form a mixture of lipid crystals for use as the medicament.

2. (Original) The process of claim 1 wherein said lipid surfactant is selected to be present in an amount of from about 99.99 to about 50 weight percent and wherein said spreading agent is selected to be present in an amount of from about 50 to about 0.01 weight percent.

3. (Original) The process of claim 1 wherein said lipid surfactant is selected to be present in an amount of from about 80 to about 99.5 weight percent and wherein said spreading agent is selected to be present in an amount of from about 20 to about 0.5 weight percent.

4. (Original) The process of claim 1 further comprising bottling said mixture within a metered dose device

5. (Original) The process of claim 1 wherein the sterols are selected from the group consisting of cholesterol, ergosterol, cholecalciferol and mixtures thereof.

6. (Original) The process of claim 1 wherein the fatty acids are selected from the group consisting of palmitic acid, oleic acid and mixtures thereof.

7. (Original) The process of claim 1 wherein the lipids are selected from the group consisting of phospholipids, neutral lipids and mixtures thereof.

8. (Original) The process of claim 7 wherein the phospholipids are selected to be any of a class known as phosphatidylcholines.

9. (Original) The process of claim 8 wherein the phosphatidylcholine is selected to be any fully saturated diacyl phosphatidylcholine.

10. (Original) The process of claim 9 wherein the fully saturated diacyl phosphatidylcholine is selected to be 1,2 dipalmitoyl phosphatidylcholine.

11. (Original) The process of claim 7 wherein the phospholipid is selected from the group consisting of diacylphosphatidylglycerol, diacylphosphatidylethanolamime, diacylphosphatidylserine, diacylphosphatidylinositol, sphingomelin, Cardiolipin, lysophospholipid, plasmalogen, diether phosphonolipid, dialkylphospholipid, and mixtures thereof.

12. (Original) The process of claim 1 wherein the carbohydrates are selected from the group consisting of glucose, fructose, galactose, pneumogalactan, dextrose and mixtures thereof.

13. (Original) The process of claim 1 wherein the protein is selected from the group consisting of albumin and pulmonary surfactant specific proteins A, B, C, D and mixtures thereof.

14. (Original) The process of claim 1 wherein the cholesteryl ester is selected from the group consisting of cholesteryl palmitate, cholesteryl oleate, cholesteryl stearate and mixtures thereof.

15. (Original) The process of claim 1 wherein the propellants are selected to be fluorocarbons.

16. (Original) The process of claim 15 wherein the fluorocarbon is selected from the group consisting of chlorofluorocarbon, hydrofluorocarbon and mixtures thereof.

17. (Original) The process of claim 1 wherein the propellant is selected to be carbon dioxide.

18. (Original) The process of claim 1 wherein the propellant is selected to be any pharmaceutical grade hypo-allergenic propellant in which the at least one surfactant and spreading agent are not soluble.

19. (Original) The process of claim 1 wherein 95 percent of said crystals demonstrate a particle size no greater than 4 microns in diameter.

20. (Original) A process for preparing an otitis media medicament comprising:

combining at least one lipid surfactant, at least one spreading agents, at least one therapeutically active agents effective in the treatment of otitis media and at least one propellants to form a mixture, said lipids and said spreading agents being selected from the group consisting of sterols, lipids, fatty acids, cholesteryl esters, phospholipids, carbohydrates, and proteins all in powder form, wherein said lipids, said spreading agents and said therapeutically active agents are insoluble in the propellants and said lipids are selected to be present in an amount effective in lowering surface tension of an air/liquid interface resident upon epithelial tissues lining mammalian eustachian tube and middle ear and said spreading agents being present in an amount effective in distributing said surfactant within said lining of the lumen and middle ear when said propellants are evaporated from said mixture to form a mixture of lipid crystals combined with said therapeutic agents for use as the medicament.

21. (Original) The process of claim 20 wherein said lipid surfactant is selected to be present in an amount of from about 99.99 to about 50 weight percent and wherein said spreading agent is selected to be present in an amount of from about 50 to about 0.01 weight percent.

22. (Original) The process of claim 20 wherein said lipid surfactant is selected to be present in an amount of from about 80 to about 99.5 weight percent and wherein said spreading agent is selected to be present in an amount of from about 20 to about 0.5 weight percent.

23. (Original) The process of claim 20 further comprising bottling said mixture within a metered dose device

24. (Original) The process of claim 20 wherein the sterols are selected from the

group consisting of cholesterol, ergosterol, cholecalciferol and mixtures thereof.

25. (Original) The process of claim 20 wherein the fatty acids are selected from the group consisting of palmitic acid, oleic acid and mixtures thereof.

26. (Original) The process of claim 20 wherein the lipids are selected from the group consisting of phospholipids, neutral lipids and mixtures thereof.

27. (Original) The process of claim 26 wherein the phospholipids are selected to be any of a class known as phosphatidylcholines.

28. (Original) The process of claim 27 wherein the phosphatidylcholine is selected to be any fully saturated diacyl phosphatidylcholine.

29. (Original) The process of claim 28 wherein the fully saturated diacyl phosphatidylcholine is selected to be 1,2 dipalmitoyl phosphatidylcholine.

30. (Original) The process of claim 26 wherein the phospholipid is selected from the group consisting of diacylphosphatidylglycerol, diacylphosphatidylethanolamime, diacylphosphatidylserine, diacylphosphatidylinositol, sphingomelin, Cardiolipin, lysophospholipid, plasmalogen, diether phosphonolipid, dialkylphospholipid, and mixtures thereof.

31. (Original) The process of claim 20 wherein the carbohydrates are selected from the group consisting of glucose, fructose, galactose, pneumogalactan, dextrose and mixtures thereof.

32. (Original) The process of claim 20 wherein the protein is selected from the group consisting of albumin and pulmonary surfactant specific proteins A, B, C, D and mixtures thereof.

33. (Original) The process of claim 20 wherein the cholesteryl ester is selected from the group consisting of cholesteryl palmitate, cholesteryl oleate, cholesteryl stearate and mixtures thereof.

34. (Original) The process of claim 20 wherein said therapeutically active agent is selected from the group consisting of anti-inflammatory, antibiotic, decongestant and gene therapy agents.

35. (Original) The process of claim 34 wherein the anti-inflammatory agent is

selected to be betamethasone.

36. (Original) The process of claim 34 wherein said antibiotic is selected from the group consisting of erythromycin, amoxicillin, zythromax, Augmentin and mixtures thereof.

37. (Original) The process of claim 34 wherein the decongestant is selected to be phenylephrine.

38. (Original) The process of claim 20 wherein the propellants are selected to be fluorocarbons.

39. (Original) The process of claim 38 wherein the fluorocarbon is selected from the group consisting of chlorofluorocarbons, hydrofluorocarbons and mixtures thereof.

40. (Original) The process of claim 20 wherein the propellant is selected to be carbon dioxide.

41. (Original) The process of claim 20 wherein the propellant is selected to be any hypo-allergenic, pharmaceutical grade propellant in which the neither the surfactant, spreading agent or therapeutically active agent are soluble.

42. (Original) The process of claim 20 wherein 95 percent of said crystals demonstrate a particle size no greater than 4 microns in diameter.

43. (Presently Amended) A process for preparing an otitis media medicament comprising:

combining at least one lipid surfactant, at least one therapeutically active agent effective in the treatment of otitis media and at least one propellants to form a mixture, said lipid surfactants being selected from the group consisting of sterols, lipids, fatty acids, cholesteryl esters, phospholipids, carbohydrates, and proteins all in powder form, wherein said lipids and said therapeutically active agents are insoluble in the propellants and said lipids are selected to be present in an amount effective in lowering surface tension of an air/liquid interface resident upon ~~epithelium~~ epithelial tissues lining ~~said~~ both mammalian eustachian tube and middle ear structures and effective in distributing said surfactant within said lining of the lumen and middle ear when said

propellants are evaporated to form an aerosolized mixture of lipid crystals combined with said therapeutic agents for use as the medicament.

44. (Original) The process of claim 43 wherein said lipid surfactant is selected to be present in an amount of from about 99.99 to about 50 weight percent and wherein said therapeutically active agent is selected to be present in an amount of from about 50 to about 0.01 weight percent.

45. (Original) The process of claim 43 wherein said lipid surfactant is selected to be present in an amount of from about 80 to about 99.5 weight percent and wherein said therapeutically active agent is selected to be present in an amount of from about 20 to about 0.5 weight percent.

46. (Original) The process of claim 43 further comprising bottling said mixture within a metered dose administration device.

47. (Original) The process of claim 43 wherein the sterols are selected from the group consisting of cholesterol, ergosterol, cholecalciferol and mixtures thereof.

48. (Original) The process of claim 43 wherein the fatty acids are selected from the group consisting of palmitic acid, oleic acid and mixtures thereof.

49. (Original) The process of claim 43 wherein the lipids are selected from the group consisting of phospholipids, neutral lipids and mixtures thereof.

50. (Original) The process of claim 49 wherein the phospholipids are any of a class known as phosphatidylcholines.

51. (Original) The process of claim 50 wherein the phosphatidylcholine is any fully saturated diacyl phosphatidylcholine.

52. (Original) The process of claim 51 wherein the fully saturated diacyl phosphatidylcholine is 1,2 dipalmitoyl phosphatidylcholine.

53. (Original) The process of claim 49 wherein the phospholipid is selected from the group consisting of diacylphosphatidylglycerol, diacylphosphatidylethanolamime, diacylphosphatidylserine, diacylphosphatidylinositol, sphingomelin, Cardiolipin, lysophospholipid, plasmalogen, diether phosphonolipid, dialkylphospholipid, and mixtures thereof.

54. (Original) The process of claim 43 wherein the carbohydrates are selected from the group consisting of glucose, fructose, galactose, pneumogalactan, dextrose and mixtures thereof.

55. (Original) The process of claim 43 wherein the protein is selected from the group consisting of albumin and pulmonary surfactant specific proteins A, B, C, D and mixtures thereof.

56. (Original) The process of claim 43 wherein the cholesteryl ester is selected from the group consisting of cholesteryl palmitate, cholesteryl oleate, cholesteryl stearate and mixtures thereof.

57. (Original) The process of claim 43 wherein said therapeutically active agent is selected from the group consisting of anti-inflammatory, antibiotic, decongestant and gene therapy agents.

58. (Original) The process of claim 57 wherein said anti-inflammatory agent is betamethasone.

59. (Original) The process of claim 57 wherein said antibioitic is selected from the group consisting of erythromycin, amoxicillin, zythromax and Augmentin.

60. (Original) The process of claim 57 wherein said decongestant is phenylephrine.

61. (Original) The process of claim 43 wherein the propellants are fluorocarbons.

62. (Original) The process of claim 61 wherein the fluorocarbon is selected from the group consisting of chlorofluorocarbon, hydrofluorocarbon and mixtures thereof.

63. (Original) The process of claim 43 wherein the propellant is selected to be carbon dioxide.

64. (Original) The process of claim 43 wherein the propellant is selected to be any pharmaceutical grade, hypo-allergenic propellant in which neither the at least one surfactant or therapeutic agent are not soluble.